URIC ACID

Specifically for use with Diatron PICTUS® 700 and PICTUS® 500 Analyzers

2°C – 8°C

REF 1419-0052 **Packaging:** 6 x 22 mL (R1) + 6 x 22 mL (R2)

Σ 1080

INTENDED USE

Reagents for In Vitro quantitative automated measurement of the concentration of Uric Acid in samples of human serum, plasma or urine from the general patient population. Measurements of Uric Acid are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as an aid in diagnosis and management of predisposition and /or confirmation of diseases and co-morbidities related to hyperuricemia / hyperuricosuria.

This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers.
For in vitro diagnostic use only by trained laboratory professionals.

CLINICAL SIGNIFICANCE

Serum: Elevated uric acid can be due to purine-rich diet, severe exercise, gout, renal failure, leukemia, multiple myeloma, polycythemia, lymphoma, other disseminated neoplasms, toxemia of pregnancy, psoriasis, gluconeogenesis Type I, Lesch-Nyhan syndrome, Down's syndrome, polycystic kidney disease, chronic lead nephropathy. Uric acid is also increased in obesity, hyperlipidemia, hypertension, atherosclerosis, diabetes mellitus, ethanol consumption, hypoparathyroidism, acromegaly, sarcoidosis and liver disease, gross tissue destruction, excessive nucleoprotein metabolism (e.g. myeloid leukemia, pernicious anemia, strychnine poisoning). Acute (sometimes dangerous) elevation follows treatment of leukemia with cytotoxic drugs. A reduction of uric acid in serum can be observed at Wilson's disease, Fanconi syndrome, Hodgkin's disease, multiple myeloma, bronchogenic carcinoma, xanthinuria, SIADH, deficiencies of adenosine deaminase, purine, nucleoside phosphorylase or low purine diet.
Urine: Uric acid is high in leukemia, gout, Lesch-Nyhan syndrome, Wilson's disease, cystinosis, viral hepatitis, sickle cell anemia, polycythemia vera. Low levels of uric acid in urine are seen at xanthinuria, folic acid deficiency, and lead poisoning.

METHOD PRINCIPLE

The URICASE/PAP method is applied. The enzymatic determination of uric acid is based on the following reactions:

$$\text{Uric acid} + H_2O + O_2 \xrightarrow{\text{Uricase}} \text{Allantoine} + CO_2 + H_2O_2$$

$$H_2O_2 + \text{4-Aminoantipyrine} + \text{TOOS} \xrightarrow{\text{Peroxidase}} \text{Quinoneimine} + 4H_2O$$

TOOS: N-ethyl-N-(2-hydroxy-3-sulphopropyl)-3-methylalanine.

The absorbance at 550/650 nm is proportional to the concentration of uric acid in the sample.

METHOD LIMITATIONS

Refer to the book "Effects of Preanalytical Variables on Clinical Laboratory Tests" for possible interference of other pharmaceutical agents in this particular test. Interference of other agents is described in the "Clinical Guide to Laboratory Tests". This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers. For additional information please contact customer support at Diatron or Medicon.

REAGENT COMPOSITION

Reagent 1 (R1)		Reagent 2 (R2)	
4-aminoantipyrine:	1 mM	Uricase:	> 260 U/L
Peroxidase:	> 15 KU/L	Non-reactive ingredients, preservative	
Non reactive ingredients, preservative.			

⚠ **WARNINGS – PRECAUTIONS**

- The reagent is designed for in vitro diagnostic use. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratory techniques. Avoid inhalation and contact with eyes and skin.
- Samples should be considered as potentially infectious. Handle with special caution.
-
- This reagent contains sodium azide (NaN_3) ≤ 0.1%. Avoid swallowing and contact of the reagent with skin and mucous membranes.
- Dispose all waste according to national laws.
- Any serious incident that may occur in relation to this device must be reported by the user to the manufacturer and the competent authority of the country in which the user and/or the patient is established!
- MSDS is available by Diatron or MEDICON upon request.

⚠ **PREPARATION**

R1 and R2 reagents ready-to-use. The vials bear barcodes for automatic recognition by Diatron Pictus® P700 / P500 analyzers.

⚠ **REAGENT DETERIORATION**

The reagents should not be used:

- When they do not exhibit the specified linearity or control values lie outside the acceptable range after recalibration.
- When they appear turbid.
- After prolonged exposure to sunlight or high temperature.

⚠ **SHELF LIFE**

Unopened the reagent is stable at 2 – 8°C up to the expiry date stated on the label. After opening it remains stable for 2 months when stored in the cooled reagent tray of the Diatron Pictus® P700 or P500 analyzers.

⚠ **SAMPLE** Serum, Li-heparin plasma or 24-hour urine may be used as specimen. Use established Good Laboratory Practices for sampling, transport and separation from blood cells. Do not use hemolyzed, contaminated or turbid sample specimens. Anti-coagulants other than Li-heparin have not been tested and should not be used. Centrifuge sample as soon as possible and store at room temperature if analysis cannot take place right after sample separation. do not freeze or refrigerate samples. Uric acid is stable in serum and plasma for 3 days at 2 – 4°C, and 6 months at -20°C. 24-hour urine samples must be tested fresh; do not freeze urine samples.

CALIBRATION Diatron offers MEDICON MEDI-CAL (code 1578-0891) traceable to SRM 909b (NIST) for serum calibration. Calibrate the assay when a new lot of reagent is installed. Perform a Reagent Blank measurement every 1 month. Calibration should also be repeated after major maintenance is performed on the analyzer, after a critical part is replaced, or when a significant shift in control values occurs. Urine Applications are pre-programmed on the analyzer to automatically acquire a calibration factor after every successful serum calibration.

QUALITY CONTROL Diatron offers MEDICON Clinical Chemistry Control Level 1 & 2 (1578-0901-12 & 1578-0902-12 respectively) for serum quality control. Control recovery should lie within the acceptable range. Results outside the acceptable range even after recalibration could be due to reagent deterioration, unsuitable storage conditions or control deterioration, instrument malfunction, or error during test procedure

MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

- Uric Acid calibrator
- Quality control material
- Diatron Pictus® analyzer
- Common laboratory equipment

REFERENCE INTERVALS

Serum or plasma:	3.6 – 8.2 mg/dl (men)	2.3 – 6.1 mg/dl (women)
Urine 24h:	250 – 800 mg (men)	250 – 750 mg (women)

Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should determine its own expected values as dictated by good laboratory practices.

⚠ **WASTE DISPOSAL**

This product contains sodium azide (NaN_3), which forms sensitive explosive compounds with copper or lead. Flush waste pipes with water after the disposal of undiluted reagent in order to avoid azide build up in the drain pipes.

SPECIFIC PERFORMANCE CHARACTERISTICS

The following values are representative of the reagent performance on Diatron Pictus® P700 or P500 analyzers. The reagent performance has been evaluated on other types of analyzers, covering all requirements of the 98/79 IVD Directive. A list of analyzers with the corresponding performance characteristics is available in the special leaflet accompanying the insert. The results taken in your laboratory may differ from these values.

Linearity	Serum: Up to 30 mg/dL	Urine: up to 300 mg/dL
Lowest detection limit:	Serum: 0.16 mg/dL	Urine: 1.71 mg/L

The lowest detection limit (LDL) is defined as the lowest concentration of analyte that is distinguishable from zero. A sample free of analyte is assayed 20 times within the assay and the LDL is calculated as the absolute mean plus three standard deviations.

Precision: Precision is estimated on two concentration levels of analyte according to CLSI protocol EP-5T (20 consecutive days, 2 runs per day, 2 repeats per run).let accompanying the insert. The results taken in your laboratory may differ from these values.

Pictus® P700 and P500			
SERUM		**URINE**	
Mean (mg/dL)	**%CV**	**Mean (mg/dL)**	**%CV**
4.30	2.70	7.25	1.35
8.70	1.80	14.6	0.49
Mean (mg/dL)	**TOTAL %CV**	**Mean (mg/dL)**	**TOTAL %CV**
4.30	4.40	7.25	1.56
8.70	2.50	14.6	1.67

INTERFERENCES - Criterion: recovery within ±10% from target value

Serum	**(**Insignificant up to)	**Urine**	**(**Insignificant up to)
Triglycerides	1000 mg/dL	Bilirubin	50 mg/dL
Hemoglobin	500 g/dL	Ascorbic Acid	05 g/L
Bilirubin	20 mg/dL	Glucose	10 g/L
Conj. Bilirubin	20 mg/dL	Creatinine	3 g/dL
Ascorbic acid	0.8 mg/dL	Urea	5g/dL

Correlation: A comparison was performed between this reagent on a Diatron Pictus® P700 and P500 analyzer, and another, commercially available product. The results were as follows:

SERUM: Y = 1.040X + 0.064	R=0.9905	N=40	Sample range = 2.38 – 9.50 mg/dL
URINE: Y = 1.044X + 0.247	R=0.9693	N=23	Sample range = 2.20 – 20.4 mg/dL

BIBLIOGRAPHY

- Tietz, NW, ed. Clinical Guide to Laboratory Tests. 3rd. ed. Philadelphia: W.B. Saunders Company Ltd., 1995.
- Burtis, CA and Ashwood, ER, ed. Tietz Textbook of Clinical Chemistry. 2nd. ed. Philadelphia: W.B. Saunders Company Ltd., 1994.
- Jacobs, DJ, Demott, WR, Grady, HJ, Horvat, RJ, Huestis, DW and Kasten, BL, JR, eds. Laboratory Test Handbook. 4th. ed. Ohio, Hudson: Lexi-Comp Inc., 1996.
- Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd. ed. Washington, DC: The American Association for Clinical Chemistry Press, 1997.

SYMBOLS

Manufacturer

In vitro diagnostic medical device

Temperature Limit

REF Catalogue Number

Caution

Contains sufficient for <n> tests

* PICTUS®: Registered Trademark of Diatron Medical Instruments Limited, Táblás utca 39, H-1097 Budapest, Hungary, used here after contractual agreement.

MEDICON HELLAS S.A. - Melitona 5-7, 153 44 Gerakas, Greece. Tel: +302106606000 - Fax: +302106612666 – www.mediconsa.com

Version 4 - Last updated 2020.06.30

CE IVD